REMARKS

Applicants would like to thank the Office for the substantive review given to this case. In the non-final Office Action, the Office rejected claims 1-42 and 51-54. More specifically:

- Claims 1-42 and 53 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter;
- Claim 53 was rejected under 35 U.S.C. § 112, sixth paragraph, as having a means plus function limitation where the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function;
- Claims 1, 7-21, 23-25, 29-36, 51-52 and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0042725 to Mayaud ("Mayaud") in view of U.S. Patent Application Publication No. 2004/0049506 to Ghouri ("Ghouri") and Applicants' Own Admission ("AOA");
- Claims 2-6, 26, 27, 41 and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Ghouri, AOA and U.S. Patent No. 6,438,407 to Ousdigian et al. ("Ousdigian");
- Claims 22, 28 and 37-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Ghouri, AOA and Official Notice;
- Claim 42 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Ghouri, AOA, Ousdigian and Official Notice.

Claims 1 and 51-54 have been amended. Support for the amendments may be found throughout the specification, and particularly at paragraphs [0022] and [0068]. No new matter has been added as a result of these amendments. Upon entry of this Amendment and Response, claims 1-42 and 51-54 will remain pending. For the reasons set forth hereinbelow, Applicants request that the rejections associated with the pending claims be withdrawn.

Rejections under 35 U.S.C. § 101

The Office rejected claims 1-42 and 53 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claims 1 and 53 have been amended to address this rejection. Claim 1 has been amended to recite a computer implemented method wherein certain recited steps are performed by a processor. Claim 53 has been amended to recite a system claim including a

processor and a computer-readable storage medium having programming instructions as recited and in communication with the processor.

Applicants respectfully submit that claims 1-42 and 53 satisfy 35 U.S.C. § 101 under the "machine-or-transformation test" as recently clarified by the U.S. Court of Appeals in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), because the claims are tied to a particular machine for meaningful and significant claim activity. Further, claim 53 as amended is patentable subject matter per *In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995). Accordingly, Applicants respectfully request that the rejections of claims 1-42 and 53 under 35 U.S.C. § 101 be withdrawn for at least this reason.

Rejections under 35 U.S.C. § 112, ¶ 6

The Office has rejected claim 53 under 35 U.S.C. § 112, sixth paragraph, as having means plus function limitations where the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. Applicants note that independent claim 54 is the only claim incorporating means plus function limitations, and addressed the rejection via amendments to claim 54. The Office asserted that Applicants are required to (1) amend the claim so that it is no longer a means plus function limitation, or (2) amend the written description of the specification to clearly link or associated the corresponding structure, material or acts to the claimed function without introducing new matter, or (3) state on the record where the corresponding structure, material or acts are set forth in the written description of the specification that perform the claimed function.

Applicants respectfully disagree with the rejection. However, to facilitate prosecution and to overcome the rejection, Applicants amend claim 54 to recite a "computer" means as the corresponding structure, material or acts that perform the claimed function. Support for this amendment is implicit in the specification and is further set forth in original claim 53, in FIG. 1, and in paragraphs [0020] and [0042] disclosing a previous computerized method and a method utilizing a logical, evidence-based process, respectively. Further, structure corresponding to claim 53 may be considered implicit throughout the written description as a skilled artisan would consider it clear that a logic or computer structure must perform the function of claim 53. *See* MPEP § 2181 (". . . disclosure of structure corresponding to a means-plus-function limitation

may be implicit in the written description if it would have been clear to those skilled in the art what structure must perform the function recited in the means-plus-function limitation"). Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, ¶ 6, be withdrawn.

Claims 1-42

Applicants submit that independent claim 1 is nonobvious over Mayaud in view of Ghouri and Applicants' Own Admission (AOA) because the cited references, either alone or in combination, fail to teach or suggest each and every limitation of claim 1. *See* MPEP § 2143 (stating that one of the elements of a *prima facie* case of obviousness under § 103(a) is that the prior art references must teach or suggest all the claim limitations). More particularly, Applicants submit that the combination of Mayaud, Ghouri and AOA fails to teach or suggest the combination of at least the following limitations of amended independent claim 1:

- identifying a medication use process associated with a pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;
- determining, by the processor, whether the medication use process will be adequate to protect patients from experiencing adverse side effects; and
- based on the determination, identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects and identifying one or more multiple redundant interventions for each failure mode.

Mayaud discloses a wirelessly deployable, electronic prescription creation system for physician use that captures a patient condition and treatment objective into a prescription and provides a patient record assembly with privacy controls, adverse indication review, and online access to drug information. *See* Mayaud at Abstract. Mayaud further describes a *condition selection* which identifies a patient condition and enables a drug to be selected for such condition by a physician. *See id.* at [0269]-[0270].

Ghouri discloses a system and method for electronic and algorithmic data mining of an individual physician's prescribing history to determine the approximate distribution of diseases within their practice population for optimizing pharmaceutical sales and marketing. *See* Ghouri at Abstract. Ghouri discloses *comparing* one drug against competitor drugs by determining

drug-drug, drug-disease, and drug-allergy interactions for a plurality of drugs, and determining a safety score for each interaction based on the severity and an expected frequency of the interaction. *See id.* at [0084].

In contrast, amended independent claim 1 recites identifying a medication use process associated with a pharmaceutical product wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product. A medication use process includes a plurality of steps, such as identifying a condition, prescribing a drug, filling out a prescription, administering the prescribed drug and monitoring a patient's reaction to the prescribed drug. In contrast, Mayaud merely discloses a prescribing operation based on a determined condition. Mayaud does not identify a medication use process as is described in reference to claim 1. Moreover, Ghouri does not describe any medication use process. Ghouri is directed to determining drug interactions between competitor drugs to determine which drug has the least severe and/or least common side effects. Ghouri does not teach or suggest identifying a medication use process as described in claim 1.

Claim 1 further recites determining, by the processor, whether the medication use process will be adequate to protect patients from experiencing adverse side effects and, based on the determination, identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects and identifying one or more multiple redundant interventions for each failure mode. The Office does not assert that either Mayaud or Ghouri teaches or discloses identifying potential failure modes where the medication use process will not be adequate. This is because neither Mayaud nor Ghouri teaches identifying potential failure modes. Rather, the Office depends on paragraphs [0002]-[0006] of Applicants' specification for such limitation, and in particular paragraphs [0003]-[0005] disclosing the FMEA system. However, these paragraphs of Applicants' specification do not teach or suggest identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects and identifying one or more multiple redundant interventions for each failure mode. Such paragraphs merely teach risk management strategies and programs that have been used to assess risk in industries including manufacturing, environmental, food industries and aviation.

Further, paragraphs [0003]-[0005] discuss (1) using a weighted analysis to address only the most undesirable adverse event and then identifying potential failures in a system which may lead to those events and (2) a Failure Mode Effect Analysis ("FMEA") process, which is an engineering technique industries have adopted that utilizes a systematic approach of identifying all potential failures in a system and then determining potential effects of each failure. Nothing in these paragraphs teaches or suggests the use of such to identify failure modes related to a medication use process that is implemented to protect patients from a risk of experiencing adverse side effects associated with use of a pharmaceutical product. Rather, the paragraphs merely disclose (1) identifying all potential failures *in a system* or (2) identifying failure modes of only the most undesirable adverse events *in a system* where a risk protection measure has not yet been implemented. The paragraphs do not disclose identification of failure modes of a *risk protection implementation subsystem*, such as the medication use process of claim 1. Moreover, nothing in these paragraphs teaches or suggests identifying multiple redundant interventions for each of the failure modes identified for the medication use process of claim 1.

Therefore, for at least the reasons set forth hereinabove, Applicants submit that claim 1 is nonobvious over the combination of Mayaud, Ghouri and AOA because the cited references fail to teach or suggest each and every limitation of claim 1. *See* MPEP § 2143. Applicants further submit that claims 2-42, which depend from and incorporate all of the limitations of claim 1, are also nonobvious over the cited references. *See* MPEP § 2143.03 (stating that if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious). Accordingly, Applicants request that the rejections associated with claims 1-42 be withdrawn.

Claims 51, 52 and 54

The Office rejected independent claims 1, 51-52 and 54 under 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Ghouri and AOA, and independent claim 54 as unpatentable over Mayaud in view of Ghouri, AOA and Ousdigian.

For the reasons discussed above with respect to claim 1, the combination of Mayaud, Ghouri and AOA fails to teach or suggest each and every limitation of independent claims 51, 52 and 54. More particularly, Applicants submit that the combination of Mayaud, Ghouri and AOA fails to teach or suggest the combination of at least the following limitations of amended independent claims 51, 52 and 54 (differences disclosed in brackets):

- [a means for] identify[ing] a medication use process associated with [for] the pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;

- [a means for] determine[ing] whether the medication use process will be adequate to protect patients from experiencing adverse side effects; and

- [a means for identifying, based on the determination] based on the determination, identify potential failure modes of the medication use process effects and identify[ing] one or more multiple redundant interventions for each failure mode.

Therefore, for at least the reasons set forth hereinabove, Applicants submit that claims 51, 52 and 54 are nonobvious over the combination of Mayaud, Ghouri and AOA because the cited references fail to teach or suggest each and every limitation of the claims. *See* MPEP § 2143. Moreover, for at least the reasons set forth hereinabove, Applicants submit that claim 54 is nonobvious over the combination of Mayaud, Ghouri, AOA and Ousdigian because the cited references fail to teach or suggest each and every limitation of the claims. *See* MPEP § 2143. Accordingly, Applicants request that the rejections associated with claims 51, 52 and 54 be withdrawn.

All of the stated grounds of rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. There being no other rejections, Applicants respectfully request that the current application be allowed and passed to issue.

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, I invite the Examiner to telephone me directly.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment and Response, or credit any overpayment, to deposit account no. 50-0436.

Respectfully submitted,
PEPPER HAMILTON LLP

Joseph T. Helmsen
Reg. No. 54,163

Pepper Hamilton LLP
One Mellon Center, 50th Floor
500 Grant Street
Pittsburgh, PA 15219
Telephone: 412.454.5000
Facsimile: 412.281.0717
Date: September 23, 2009